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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

21874 7590 01/09/2007  
EDWARDS & ANGELL, LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
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SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
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1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



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09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

7590 06/20/2006  
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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/869,098	Applicant(s) TOYODA ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>Waf</i>

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-8,11 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,8,11 and 17 is/are rejected.
- 7) ☒ Claim(s) 5,7 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Receipt is acknowledged of the papers filed 3/27/2006 in which claims 1, 6-8 and 11 were amended and claims 2-4 were cancelled. Claims 1, 5-8, 11 and 17 are pending and under examination in the instant Office Action.

Any rejection made in the previous Office Action not recited herein has been withdrawn.

**Claim Objections**

Claim 11 is objected to because of the following informalities: Claim 11 recites the phrase "wherein the part of the base sequence consists of nucleotides 255 to 430 of EQ ID NO: 1" in lines 9-23, and should instead read "wherein the part of the base sequence consists of nucleotides 255 to 430 of [[EQ]] SEQ ID NO: 1." Appropriate correction is required.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6, 8, 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This a new rejection not necessitated by Applicant's amendment.

Claim 6 recites "[t]he recombinant vector described in claim 5, which comprises a DNA comprising a structural gene under control of the human UCP-2 promoter region" in lines 1-3. Claim 6 is vague and indefinite in that it is unclear how a structural gene, which includes intron and exon sequences, as well as 5' regulatory regions and 3' untranslated regions, can be under the control of a human UCP-2 promoter. Which components of the gene are under the control of the human UCP-2 promoter? Does Applicant intend that the DNA of a coding region of a structural gene is under control of the human UCP-2 promoter or does Applicant intend that the whole structural gene is under the control of the human UCP-2 promoter region?

Claim 8 recites the phrase "[a] method for screening for a compound or its salt that promotes or inhibits a human UCP-2 promoter activity, which comprises: a. measuring the expression level of structural gene in a transformant with a human UCP-2 promoter sequence" in lines 1-4. Claim 8 is vague and indefinite in that it is unclear how the expression level of

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structural gene is measured. Does Applicant intend such a method wherein the expression level of a reporter molecule is measured or does Applicant intend that the gene itself is measured?

Claim 11 recites the phrase "a structural gene inserted downstream of the human UCP-2 promoter" in line 29. Claim 11 is vague and indefinite in that it is unclear whether Applicant intends an entire structural gene, including intron and exon sequences, as well as 5' regulatory regions and 3' untranslated regions, located downstream of the human UCP-2 promoter, or whether Applicant intends a reporter molecule operatively linked to a human UCP-2 promoter region?

Claim 17 recites "[t]he kit of claim 11, wherein the structural gene is a luciferase gene" in lines 1-2. Claim 17 is also vague and indefinite for reasons as explained for claim 11, above.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lewin (Genes V, Oxford University Press and Cell Press, pages 767-796, copyright 1994) as evidenced by GenBank entry Accession No. NM\_003355. This is a new rejection necessitated by Applicant's amendment.

Lewin teaches an isolated DNA comprising a human uncoupling protein-2 (UCP-2) promoter region which consists of all or a part of a base sequence consisting of nucleotides 1-2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255-1857 of SEQ ID NO: 1, nucleotides 571-2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1 (see especially page 781, second column and Figure 27.11). Isolated chromosome 11 is a DNA comprising a human UCP-2 promoter region consisting of all or part of the base sequence consisting of nucleotides 1-2270 of SEQ ID NO: 1, wherein the part of the base sequence is each of the parts recited in the claim. The UCP-2 promoter region is

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present on chromosome 11 as evidenced by GenBank entry Accession No. NM\_003355.

***Allowable Subject Matter***

Claims 5 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 5 and 7 are drawn to a recombinant vector comprising the DNA described in claim 1 (claim 5) and a transformant transformed with such a vector (claim 7). Lewin teaches an isolated DNA comprising a human uncoupling protein-2 (UCP-2) promoter region, which consists of all or a part of a base sequence consisting of nucleotides 1-2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255-1857 of SEQ ID NO: 1, nucleotides 571-2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1, but Lewin does not teach such an isolated DNA wherein the DNA is a recombinant vector.



### Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

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the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

June 8, 2006

~~NANCY VOGEL~~  
~~PRIMARY EXAMINER~~

*N.V.*  
NANCY VOGEL  
PRIMARY EXAMINER